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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE		
	Application Number	**09/527,558**
	Filing Date	**March 16, 2000**
	First Named Inventor	**PFIRRMANN**
	Group Art Unit	**1623**
	Examiner Name	**L. MAIER**
	Attorney Docket Number	**1194-153**
Title of the Invention: **ANTICOAGULANT/STERILIZING COMPOSITIONS AND METHODS**		

REQUEST FOR RECONSIDERATION

ATTN: Box AF
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In an Office Action dated September 19, 2001, claims 21-23 were withdrawn from consideration by the examiner as being directed to an invention that is independent or distinct from the originally claimed invention. The final rejection of claims 1-15, all of the remaining claims pending in the above-identified patent application, was maintained.

Applicant respectfully requests reconsideration of this application and allowance of the claims, as previously amended on January 5, 2001, in view of the following remarks.

Claims 1-15 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Lehner, PCT Application, WO 98/28027, in view of Reinmuller, U.S. Patent No. 5,077,281. Claims 1, 14, and 15 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Lehner and Reinmuller further in view of Ito et al (U.S. Patent 5,167,960).

Claim 1 recites a method of preventing thrombosis formation on a liquid-contacting surface of a liquid delivery system comprising a regimen selected from either:

A. forming a seal in the liquid delivery system between delivery of liquids using a thrombosis-preventing liquid containing taurolidine, taurultam or a mixture thereof and an additional anticoagulant agent other than taurolidine or taurultam:

B. first contacting the surface with a solution containing a thrombosis-preventing amount of an anticoagulant agent other than taurolidine or taurultam and thereafter contacting the surface with a solution containing taurolidine, taurultam or a mixture thereof, and repeating these contacting steps between delivery of liquids to the patient.

It has been found that by forming a seal with a thrombosis-preventing liquid as set out in the first regimen, effective anti-thrombotic action can be achieved with unexpectedly small quantities of the liquid. Furthermore, with respect to the second regimen, it has been found that by administering the solutions intermittently, using a two step process, possible interaction between the added anticoagulants and taruolidine/taurultam are avoided.

Lehner discloses flushing or sealing a liquid delivery system with taurolidine or taurultam for the purpose of combating infection or sepsis. Reinmuller discloses the use of taurolidine or taurultam as an anticoagulant. Although Reinmuller mentions that taurolin may be used together with known anti-coagulants such as heparin, Reinmuller does not teach or suggest use of the combined solution for the flushing or sealing of a delivery system.

Applicable case law holds that in order to render a claim obvious, the prior art must teach or suggest all of the features of the claim and their combination to a person of ordinary skill in the art. In the present case, there is no motivation in the prior art for the proposed combination. Lehner does not serve the same purpose or function as the present invention. Lehner is concerned with the prevention of infection or sepsis, while the present invention is directed to the prevention of thrombosis. There would be no motivation or suggestion for one

seeking to prevent thrombosis to look to the teachings of Lehner. Furthermore, there would be no motivation or suggestion to combine the teachings of Lehner with Reinmuller to add an additional coagulant, as required by the present invention, because Lehner is not concerned with anticoagulation.

The Examiner appears to rely only on the fact that taurolin derivatives exhibit both infection fighting and anticoagulant properties for the claim that the present invention would be obvious to one of skill in the art. However, no combination of the prior art would result in the present invention as specified in the first regimen of claim 1, since none of the prior art suggest sealing a delivery system with a solution containing taurolidine or taurultam combined with an additional coagulant to prevent thrombosis formation.

The second regimen of claim 1 discloses a method of preventing thrombosis formation in a liquid-delivery system by first contacting the surface with a solution containing a thrombosis-preventing amount of an anticoagulant agent other than taurolidine or taurultam and then contacting the surface with a solution containing taurolidine, taurultam or a mixture thereof and repeating the contacting steps between delivery of liquids to the patient. Thus, the second regimen of claim 1 is a two step process wherein the surface is contacted *first* with an anticoagulant and *second* with a taurolidine or taurultam solution.

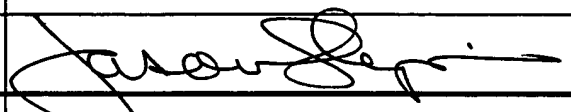
Neither reference suggests repeating such a two-step process between administration of liquids to the patient to prevent thrombosis.

Furthermore, as the examiner pointed out, Reinmuller teaches that a *single contact* with taurolin is continuously effective to prevent coagulation on a surface after implantation. See Col. 4 lines 41-47. Thus, Reinmuller actually teaches away from the repetitive two-step process as set out in the second regimen.

Accordingly, withdrawal of the rejection of claim 1 under §103(a) is respectfully requested. Claims 2-15 depend from claim 1 and are submitted to be patentable over the applied art for the reasons set forth above in connection with claim 1 as well as for the additional features they recite.

With regard to the rejection of Claims 1, 14 and 15 under 35 U.S.C. §103(a) over Lehner and Reinmuller in view of Ito, et al, Applicant notes that Ito discloses the use of hirudin or a hirudin derivative such as a thrombi-resistant substance, but does not remedy the basic deficiencies of Lehner and Reinmuller discussed above. Accordingly, no combination of the cited references would result in the method as set out in Claims 1, 14, and 15.

In view of the above, Applicant submits that the subject application is in condition for allowance. Favorable reconsideration and an early indication of allowability are respectfully requested.

<table>
<tr><td colspan="6">RESPECTFULLY SUBMITTED,</td></tr>
<tr><td>NAME AND REG. NUMBER</td><td colspan="5">Jason M. Shapiro, Registration No. 35,354</td></tr>
<tr><td>SIGNATURE</td><td colspan="2">  </td><td>DATE</td><td colspan="2">December 19, 2001</td></tr>
<tr><td>Address</td><td colspan="5">Rothwell, Figg, Ernst & Manbeck
Suite 701-East, 555 13th Street, NW</td></tr>
<tr><td>City</td><td>Washington</td><td>State</td><td>D.C.</td><td>Zip Code</td><td>20004</td></tr>
<tr><td>Country</td><td>U.S.A.</td><td>Telephone</td><td>202-783-6040</td><td>Fax</td><td>202-783-6031</td></tr>
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